What is claimed is:

1. A method for introducing an infusion device into a subcutaneous layer of skin of a patient, comprising:

providing an infusion device preloaded onto a needle of an insertion device so that the needle extends through a cannula of the infusion device;

positioning the insertion device adjacent to the skin of the patient;

introducing the cannula of the infusion device into a subcutaneous layer of skin of a patient using the needle of the insertion device; and

upon full insertion of the cannula by the insertion device and the insertion device reaching a trigger state, automatically retracting the needle of the insertion device while leaving the infusion device positioned on the skin of the patient.

2. The method of claim 1, wherein the step of loading further comprises coupling a cap to the insertion device.

3. The method of claim 2, further comprising removing the cap prior to introducing the cannula into the subcutaneous layer of skin of the patient.

4. The method of claim 1, wherein the infusion device includes a site having the cannula, and a set, and the method further comprises coupling the set to the site of the infusion device positioned on the skin of the patient.

5. The method of claim 4, wherein the step of coupling the set to the site of the infusion device further comprises:

positioning the set in an unlocked position over the site;

positioning the set onto the site; and

moving the set from the unlocked position to a locked position to couple the set to the site and to introduce a needle of the set into a reservoir defined by the site.

6. The method of claim 5, wherein the step of moving further comprises sliding a first member of the set relative to a second member of the set to move the set from the unlocked position to the locked position.

7. The method of claim 5, further comprising moving the set from the locked position to the unlocked position.

8. The method of claim 7, further comprising:

reorienting the set rotationally relative to the site; and

moving the set from the unlocked position to the locked position to recouple the set to the site and to reintroduce a needle of the set into a reservoir defined by the site.

9. The method of claim 1, further comprising providing a sleeve coupled to the insertion device to hide the needle prior to retraction.

10. An apparatus for delivery of a substance to a subcutaneous layer of skin of a patient, the apparatus comprising:

an insertion device for introducing an infusion device into a subcutaneous layer of skin of a patient, the insertion device including a housing defining an internal cavity, a needle coupled to the housing, and a member configured to move the needle into a retracted state; and

an infusion device including a site having a base positionable relative to skin of a patient, a cannula extending generally perpendicularly to the base and configured to be introduced into a subcutaneous layer of skin of the patient using the needle of the insertion device, and a diaphragm coupled to the base and defining an internal reservoir;

wherein the needle of the insertion device extends through the diaphragm and the cannula of the site to couple the site to the insertion device; and

wherein the insertion device includes a cap to seal the insertion device prior to removal of the cap from the insertion device.

11. The apparatus of claim 10, further comprising a set including a first member including a hollow needle and a second member defining an aperture configured to accept the site.

12. The apparatus of claim 11, wherein the set includes tubing that is in fluid communication with the needle.

13. The apparatus of claim 12, wherein the set is mounted onto the site.

14. The apparatus of claim 10, further comprising an adhesive portion coupled to the infusion device, wherein the adhesive portion couples the infusion device to the skin of the patient.

15. The apparatus of claim 10, further comprising a tamper-evident band coupled by tabs to the cap, wherein the tabs are broken as the cap is removed from the insertion device and the tamper-evident band remains coupled to the insertion device.

16. An apparatus for delivery of a substance to a subcutaneous layer of skin of a patient, the apparatus comprising:

a site defining a central aperture and a cavity, a diaphragm positioned in the cavity and defining a reservoir, and a cannula extending through the central aperture and having a first end that is fluidly coupled to the reservoir of the diaphragm; and

an insertion device including a housing, a hub coupled to the housing and defining an interior passage, a needle hub including a needle, the needle hub being positioned in the interior passage of the hub so that the needle hub is held in a fixed position relative to the hub and the housing, and a spring engaging the needle hub;

wherein the site is loaded onto the insertion device by introducing the diaphragm and the cannula of the site onto the needle of the insertion device; and

wherein the housing, hub, and needle hub are movable to introduce the needle of the needle hub and associated cannula of an infusion device into a subcutaneous layer of

skin, and wherein, upon the needle and associated infusion device being fully inserted into the subcutaneous layer of skin, the needle hub is slideable relative to the hub, and the needle hub including the needle are automatically moved by the spring through the passage of the hub to a retracted state, leaving the infusion device positioned on the skin of the patient.

17. The apparatus of claim 16, further comprising a sleeve coupled to the housing to hide the needle prior to retraction.

18. The apparatus of claim 16, further comprising a set including first and second members, the first member including a hollow needle fluidly coupled to an access port, and the second member defining an opening extending through the second member, and the first and second members being slideable relative to one another between an unlocked position and a locked position, wherein the set, in the unlocked position, is positionable on the site so that at least a portion of the site is received in the opening of the second member of the set, and the first member is slideable relative to the second member to move from the unlocked to the locked position to couple the set to the site, and as the first member is slid towards the second member the needle of the first member is introduceable into the reservoir of the diaphragm.

19. The apparatus of claim 18, wherein the diaphragm of the site is a single unit including an upper end that is pierced by the needle of the insertion device, and including a side wall that is pierced by the hollow needle of the first member of the set.

20. The apparatus of claim 16, further comprising further comprising an adhesive portion coupled to the site, wherein the adhesive portion couples the site to the skin of the patient.

21. A method for introducing an infusion device, comprising:
uncapping the insertion device to place the insertion device in a delivery state;

positioning the insertion device adjacent to skin;

moving a needle of the insertion device from the delivery state to the trigger state to thereby introduce a cannula of the site into the skin; and

automatically retracting the needle to place the insertion device in a retracted state.

22. The method of claim 21, further comprising:

preloading the site onto the needle of the insertion device; and

capping the insertion device to place the device in a ship state.

23. The method of claim 21, further comprising:

positioning a set of the infusion device over the site at a desired orientation with respect to the site; and

moving the set from an unlocked position to a locked position to couple the set to the site.

24. The method of claim 21, further comprising providing a tamper-evident seal on the insertion device.